## REQUEST FOR RECONSIDERATION

Applicants are amending original claim 1 to incorporate the limitations of original claim 3. Applicants also are canceling original claim 3, without prejudice. Moreover, Applicants are amending the specification to capitalize the trademark THORALON® and to include a generic description after the use of the trademark THORALON®. Applicants are including a marked-up copy of amendments to the claims and specification, with this responsive amendment. No new matter is added by the foregoing amendments and these amendments are fully supported by the specification. Applicants respectfully request that the Examiner reconsider the above-captioned patent application in view of the foregoing amendments and the following remarks.

## REMARKS

1. Objections and Rejections

The drawings stand objected to as allegedly informal. The specification stands objected to as allegedly including the trademark THORALON® without capitalizing the trademark and without including a generic description after the trademark. Claims 1-20 stand rejected under 35 U.S.C. § 112, §2 as allegedly indefinite. Claims 1-20 also stand rejected under 35 U.S.C. § 101, as allegedly improperly defining a process. Moreover, Claims 1, 2, 4-6, 8-10, 12, 16, and 18-20 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Patent No. 5, 298,276 to Jayaraman. Claims 1, 3, 5, 7, 11, and 46-49 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Patent No. 5,855,598 to Pinchuk. Claims 13-15 and 17 also stand rejected under 35 U.S.C. § 103(a), as allegedly rendered obvious by Jayaraman in view of Thoratec Products Information. Applicants respectfully traverse.

2. Drawing Objections

The drawings stand rejected as allegedly informal. Applicants respectfully disagree.

Specifically, this application was filed on August 20, 2001, i.e., after November 29, 2000. With respect to applications filed on or after November 29, 2000, the PTO no longer requires that the drawings be formal drawings. In contrast, the standard for drawings included in applications filed on or after November 29, 2000, is whether the drawings are satisfactory for reproduction. See e.g., 37 C.F.R. § 1.84. If the drawings are not satisfactory for reproduction

purposes, the Office of Initial Patent Examination (OIPE) will issue a Notice to File Corrected Papers. Nevertheless, if the drawings are satisfactory for reproduction purposes, the application will be examined. Because OIPE did not mail a Notice to File Corrected Papers in this application, Applicants maintain that the drawings in this application are suitable for reproduction. Therefore, Applicants respectfully request that the Examiner withdraw the objection to the drawings as allegedly informal.

3. Specification Objections

The specification stands objected to as allegedly including the trademark THORALON® without capitalizing the trademark and without including a generic description after the trademark. Applicants respectfully traverse.

Specifically, Applicants have amended the specification to replace the word "Thoralon®" with the phrase "THORALON® biomaterial." Therefore, Applicants respectfully request that the Examiner withdraw the objections to the specification.

4. 35 U.S.C. § 112, ¶2, and 35 U.S.C. § 101

Claims 1-20 stand rejected as allegedly indefinite and as allegedly improperly defining a process. Specifically, the Office Action asserts that "claim 1 provides for the use of a cold zone, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how its use is actually practiced." Office Action, Page 4, Lines 9-13. Applicants respectfully disagree.

Specifically, claims 1-20 are apparatus claims for a vascular graft, and are not directed toward a method of using the vascular graft. (Emphasis added.) As such, claims 1-20 do not encompass any method or process, and Applicants believe that the indefiniteness rejection is not appropriate. Nevertheless, solely to clarify the claimed apparatus, Applicants are amending claim 1 to remove the phrase "said core zone configured for use in a vessel having an internal diameter of more than 2 mm." Therefore, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection of claims 1-20.

5. 35 U.S.C. § 102(b)

Claims 1, 3, 5, 7, 11, and 46-49 stand rejected as allegedly anticipated by Pinchuk, and claims 1, 2, 4-6, 8-10, 12, 16, and 18-20 stand rejected as allegedly anticipated by

Jayaraman. "A claim is anticipated if and only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP 2131. The Office Action alleges that Pinchuk describes each and every element as set forth in claims 1, 3, 5, 7, 11, and 46-49. The Office Action also alleges that Jayaraman describes each and every element as set forth in claims 1, 2, 4-6, 8-10, 12, 16, and 18-20. Applicants respectfully traverse/

a. Pinchuk

Claims 1, 3, 5, 7, 11, and 46-49 stand rejected as allegedly anticipated by Pinchuk. Applicants have amended original claims 1 and 46 to describe that the vascular graft comprises "a first non-porous coating disposed on said first surface and permeating into at least a portion of said core zone, wherein said first coating comprises at least one polyurethane." (Emphasis added.) See, e.g., Appl'n, Page 9, Lines 20-22. For example, the first non-porous coating may be disposed on the first surface, and a portion of the first non-porous coating may permeate the entire thickness of the core zone, such that this portion of the first non-porous coating forms a non-porous coating on the second surface.

In contrast, Pinchuk describes a graft which may include a trunk component 101c, and trunk component may include a tubular supporting component 121c. The graft also may include an exterior liner 122 which engages tubular supporting component 121c, and an interior liner 123 located interiorly of exterior liner 122. Exterior liner 122 may be made of a polymeric material, such as polyethylene terephthalate, and interior liner 123 may be made of a polyurethane. See, e.g., Pinchuk, Column 14, Lines 40-52. Nevertheless, although interior liner 123 may be made of a polyurethane, interior liner 123 does not include a coating of polyurethane, such that the coating permeates into exterior liner 122. Thus, Pinchuk fails at least to describe that the vascular graft comprises "a first non-porous coating disposed on said first surface and permeating into at least a portion of said core zone, wherein said first coating comprises at least one polyurethane," as described in amended claims 1 and 46. Therefore, Applicant respectfully requests that the Examiner withdraw the anticipation rejection of claims 1 and 46 in view of Pinchuk.

Claims 3, 5, 7, 11, and 47-49 depend from amended claims 1 and 46, respectively. Therefore Applicants respectfully request that the Examiner also withdraw the anticipation rejection of claims 3, 5, 7, 11, and 47-49 in view of Pinchuk.

b. Jayaraman

Claims 1, 2, 4-6, 8-10, 12, 16, and 18-20 stand rejected as allegedly anticipated by Jayaraman. Applicants have amended original claim 1 to incorporate the limitations of original claim 3. As such, amended claim 1 describes that the vascular graft comprises "a core zone comprising a PET fabric said core zone having a first surface and a second surface opposing said first surface, wherein the first surface is a blood interface surface." The Office Action does not allege that original claim 3 is anticipated by Jayaraman, and Applicant has amending original claim 1 to incorporate the limitations of original claim 3. Therefore, Applicant respectfully requests that the Examiner withdraw the anticipation rejection of claim 1 in view of Jayaraman.

Claims 2, 4-6, 8-10, 12, 16, and 18-20 depend from amended claim 1. Therefore Applicants respectfully request that the Examiner also withdraw the anticipation rejection of claims 2, 4-6, 8-10, 12, 16, and 18-20 in view of Jayaraman.

6. 35 U.S.C. § 103(a)

Claims 13-15 and 17 also stand rejected as allegedly rendered obvious by Jayaraman in view of Thoratec Products Information. Nevertheless, as described above, Applicants have amended original claim 1 to incorporate the limitations of original claim 3. As such, amended claim 1 describes that the vascular graft comprises "a core zone comprising a PET fabric said core zone having a first surface and a second surface opposing said first surface, wherein the first surface is a blood interface surface." (Emphasis added.) The Office Action does not allege that Jayaraman describes that "the first surface is a blood interface surface," as set forth in original claim 3 and amended claim 1. Moreover, the Office Action does not allege that Thoratec Products Information or any other reference supplies this missing element. Claims 13-15 and 17 depend from amended claim 1. "If an independent claim is non-obvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." MPEP 2143.03 (citations omitted). Therefore, Applicants respectfully request that the Examiner withdraw the obviousness rejection of claims 13-15 and 17.

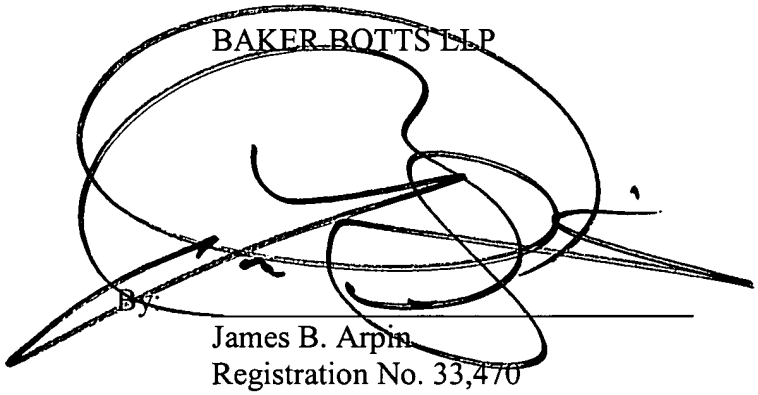
## CONCLUSION

Applicants respectfully submit that this application is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that an interview with Applicants' representatives, either in person or by telephone, would expedite prosecution of this

application, we would welcome such an opportunity. Applicants believe that no fees are due as a result of this responsive amendment. Nevertheless, in the event of any variance between the fees determined by Applicants and those determined by the U.S. Patent and Trademark Office, please charge any such variance to the undersigned's Deposit Account No. 02-0375.

Respectfully submitted,

BAKER BOTTS LLP



Dated: May 21, 2003

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Enclosure

MARKED-UP COPY OF AMENDMENTS TO THE SPECIFICATION AND CLAIMS

IN THE SPECIFICATION:

Please amend the fourth paragraph on page 2, the first paragraph on page 3, the second paragraph on page 3, the third paragraph on page 3, the fourth paragraph on page 4, the fifth paragraph on page 4, the sixth paragraph on page 4, the first paragraph on page 5, the fourth paragraph on page 5, the sixth paragraph on page 5, the first paragraph on page 6, the third paragraph on page 6, the fourth paragraph on page 6, the fifth paragraph on page 6, the fourth paragraph on page 10, the second paragraph on page 11, the first paragraph on page 12, the second paragraph on page 14, and the fourth paragraph on page 14, as follows:

The present invention is directed to grafts, such as stent grafts, made of fabrics coated with unique polyurethanes, such as [Thoralon] THORALON® biomaterial, manufactured by Thoratec Corporation, having a principle place of business in Pleasanton, CA, which provide a compliant, strong and impermeable barrier. Grafts according to the invention are particularly useful for the repair of vascular defects in large vessels, such as AAA. However, grafts coated according to the invention are not limited to AAA repair, and may be used in a variety of applications, including vascular grafts (including [endolumenal] endoluminal stent grafts) and vascular patches for any area of the body. Grafts according to the present invention provide good and physiologic biocompatibility, biostability, compliance, and strength.

In one embodiment of the invention, a vascular graft, such as an AAA stent graft, comprises a core zone or layer comprising a PET fabric. The core zone has a first surface and a second surface opposing the first surface. A non-porous or pore-free coating is disposed on at least the first surface. The coating comprises at least one polyurethane. Preferably the polyurethane is a polyurethane urea, and, most preferably, is [Thoralon] THORALON® biomaterial. The coating provides a barrier to prevent fluids from leaking through the pores of the PET fabric core zone. The core zone is preferably configured for use in a vessel having an internal diameter of more than 2 mm, and, more preferably, is configured for use in an abdominal aorta having an internal diameter of more than 6 mm.

Another embodiment of the invention provides a method for sealing the pores of a porous PET graft comprising the step of coating at least one surface of the graft with a polymer composition to produce a pore-free coat on the surface. The graft is preferably configured for use in a vessel having an internal diameter of more than 2 mm and, more preferably, is

configured for use in an abdominal aorta having an internal diameter of more than 6 mm. The polymer composition comprises at least one polyurethane. The polyurethanes are segmented and comprise a soft segment and a hard segment. Preferably, the polymer composition is [Thoralon] THORALON® biomaterial.

Methods for forming a vascular graft are also provided. For example, another embodiment of the invention provides a method for making a vascular prosthesis comprising the steps of providing a core zone or layer comprising a PET fabric, the core zone having a first surface and a second surface opposing the first surface; and coating at least the first surface of the core zone with a polymer composition to produce a pore-free coat on the surface. As with the previous embodiment, the polymer composition comprises at least one polyurethane and, most preferably, is [Thoralon] THORALON® biomaterial. The core zone is preferably configured for use in a vessel having an internal diameter of more than 2 mm. Preferably, the vascular graft is an AAA graft and the core zone is configured for use in an abdominal aorta having an internal diameter of more than 6 mm.

The present invention is directed to vascular grafts made of porous fabrics, such as PET, coated with [Thoralon] THORALON® biomaterial or other suitable polyurethanes, to prevent leakage of fluid through the pores of the graft. Specifically, the present invention uses blood-compatible polyurethanes, such as [Thoralon] THORALON® biomaterial, as coatings for the blood-contacting textiles. Coated textiles according to the invention have improved impermeability (*i.e.*, are less prone to allow leakage of fluids, such as serum or water, through the body of the graft, both long and short term). The present invention solves the problem of seepage between the graft and aorta through the pores of the fabric occurring with currently available coated PET grafts. The coatings of the invention may be used to coat other grafts, including, but not limited to, ePTFE (expanded polytetrafluoroethylene) grafts.

Because polyurethanes have very low water permeability, they can effectively seal a textile. Furthermore, polyurethanes, such as [Thoralon] THORALON® biomaterial, possess a number of desirable properties such as biostability, compliance, biocompatibility, blood compatibility and strength, which are important in many vascular applications. As such, coated textiles according to the invention provide improved blood compatibility, as well as strong and compliant reinforcement or replacement of the diseased area. Accordingly, grafts coated according to the invention may be used in a variety of applications, including vascular

grafts, stent grafts and vascular patches. Grafts according to the invention are particularly useful in the repair of AAA.

Grafts according to the invention provide a number of advantages. By using a polymer, preferably a polyether urethane urea such as [Thoralon] THORALON® biomaterial, to seal the pores of a woven fabric graft, a blood compatible prosthesis is provided. Graft coatings need to be blood compatible because they come into contact with blood. In addition, the coatings of the invention adhere to the graft, seal the pore openings, and maintain their mechanical function (*e.g.*, prevent seepage between the graft and artery) *in vivo* for a period of years.

The coatings of the invention can perform the necessary sealing function at low thicknesses. Ideally, the profile of a graft must be thin to allow for the smallest possible endolumenal intervention. [Thoralon] THORALON® biomaterial has been successfully applied as thinly as 4-5 microns. Depending on the size of the pore which needs to be sealed, even thinner applications may be achieved.

Coatings according to the invention, such as [Thoralon] THORALON® biomaterial coatings, not only provide a non-thrombogenic and an improved blood-compatible lumen surface, but may also be used as a drug delivery vehicle *(e.g.,* deliver a pharmacological agent) and as a surface-modifying coating to alter mechanical properties such as compliance and wear resistance. Also, [Thoralon] THORALON® biomaterial may be applied as a foam to promote cell adhesion (such as endothelial cells) to form a neointima in all vascular graft applications.

A preferred material for use as a coating according to the invention is [Thoralon] THORALON® biomaterial. [Thoralon] THORALON® biomaterial [(Thoratec Corporation, Pleasanton, CA)] is a polyetherurethane urea blended with a siloxane containing surface modifying additive, and has been demonstrated to provide effective sealing of textile grafts. [Thoralon] THORALON® biomaterial can be obtained from Thoratec Corporation, Pleasanton, CA. Specifically, [Thoralon] THORALON® biomaterial is a mixture of base polymer BPS-215 and an additive SMA-300 in dimethylacetamide (DMAC) solvent. The concentration of additive is preferably in the range of 0.5% to 5% by weight of the base polymer.

The BPS-215 component (Thoratec Corporation, Pleasanton, CA) used in [Thoralon] THORALON® biomaterial is a segmented polyether urethane urea containing a soft

segment and a hard segment. The soft segment is made of polytetramethylene oxide (PTMO) and the hard segment is made of 4,4'-diphenylmethane diisocyanate (MDI) and ethylene diamine (ED).

[Thoralon] THORALON® biomaterial is FDA approved for use in certain vascular applications and has been shown to be safe and effective in a variety of critical applications because it offers thromboresistance, high tensile strength, and superb flex life. [Thoralon] THORALON® biomaterial has been shown to be biostable and useful *in vivo* in long term blood contacting applications requiring biostability and leak resistance for periods exceeding one year or more. [Thoralon] THORALON® biomaterial has been shown to reduce platelet deposition and binding on blood contacting surfaces of extracorporeal circuits in patients undergoing cardiopulmonary bypass. Because of its flexibility, [Thoralon] THORALON® biomaterial is particularly beneficial in larger vessels, such as the abdominal aorta, where elasticity and compliance is essential.

[Thoralon] THORALON®['s] biomaterial' lower water absorption contributes to enhanced *in vivo* stability, while its lower critical surface tension and longer Lee White Clotting Times demonstrate improved blood compatibility and thromboresistance (Table 1).

In addition to [Thoralon] THORALON®, biomaterial other polyurethane ureas may be used to coat the fabric component of the graft. For example, BPS-215 with a capping ratio (MDI/PTMO mole ratio) ranging from about 1.0 to about 2.5 may be used. Such polyurethane ureas preferably comprise a soft segment, and a hard segment comprising a diisocyanate and diamine. For example, polyurethane ureas with soft segments such as polyethylene oxide, polypropylene oxide, polycarbonate, polyolefin, polysiloxane (*e.g.*, polydimethylsiloxane), and other polyether soft segments made from higher homologous series of diols may be used. Mixtures of any of the soft segments may also be used. The soft segments may also have either alcohol or amine end groups. The molecular weight of the soft segments may vary from about 500 to about 5,000 g/mole, and preferably is about 2,000 g/mole.

In a preferred embodiment, the coating comprises [Thoralon] THORALON® biomaterial. However, the coating may comprise one or more polyurethanes, or mixtures and combinations thereof. Preferably, the polyurethanes each comprise a soft segment and a hard segment. As discussed above, the soft segment may comprise one or more compounds selected from the group consisting of polytetramethylene oxide, polyethylene oxide, polypropylene oxide,

polycarbonate, polyolefin, polysiloxane (*e.g.*, polydimethylsiloxane), polyether soft segments made from higher homologous series of diols, and mixtures and combinations thereof. The soft segments may also have either alcohol or amine end groups.

Another embodiment of the invention is directed to a method for sealing the pores of a porous PET graft comprising the step of coating at least one surface of the graft with a polymer composition to produce a pore-free coat on the surface, the polymer composition comprising at least one polyurethane, or mixtures and combinations of polyurethanes, as described herein. The graft is preferably configured for use in a vessel or to repair a vessel having an internal diameter of more than 2 mm. More preferably, the vessel has an internal diameter of more than 3 mm, and, most preferably, more than 6 mm. Preferably, the graft comprises an AAA stent graft and the polymer composition comprises [Thoralon] THORALON® biomaterial.

The invention is also directed to methods of making PET grafts having reduced permeability. In making such grafts, adhesion of the polyurethane to the textile is a critical parameter. To enhance adhesion, the textile may be pretreated by washing the textile in methylene chloride, acetone, or another suitable agent. Alternately, additives to the polyurethane may be used to promote effective bonding. Examples include, but are not limited to, [Thoralon] THORALON® biomaterial with and without siloxane additive (SMA).

In this example, the water permeability of uncoated graft fabric was compared to fabrics coated with [Thoralon] THORALON® biomaterial. Testing was performed in accordance with Association of the Advancement of Medical Instrumentation, ANSI/AAMI VP20, 1994, with the exception of the diameter of the opening, as discussed below. The uncoated fabric tested was made of polyester, and more specifically, was fabric from an AAA graft (AneuRx™ polyester fabric graft, supplied by Medtronic, Inc., Minneapolis, MN). This same fabric was also coated with about a 12 micron layer of [Thoralon] THORALON® biomaterial on both sides.

As can be seen from Table 2, there was no flow of water through the [Thoralon] THORALON® biomaterial coated fabric, confirming that [Thoralon] THORALON® biomaterial coatings can dramatically improve the water permeability of porous graft fabrics.

IN THE CLAIMS:

Please cancel original claim 3, without prejudice.

Please amend original claims 1 and 46, as follows:

1. (amended) A vascular graft comprising:

a core zone comprising a PET fabric[, said core zone configured for use in a vessel having an internal diameter of more than 2 mm,] said core zone having a first surface and a second surface opposing said first surface, wherein the first surface is a blood interface surface; and

a first non-porous coating disposed on [at least] said first surface and permeating into at least a portion of said core zone, wherein said first coating comprises at least one polyurethane.

46. (amended) A method for repairing a defective vessel in an individual, said vessel having an internal diameter of more than 2 mm, comprising the step of:

reinforcing or replacing said defective vessel with a vascular graft comprising:

a PET fabric core zone, [and a polyurethane coating disposed on at least one surface of said core zone] said core zone having a first surface and a second surface opposing said first surface; and

a first non-porous coating disposed on said first surface and permeating into at least a portion of said core zone, wherein said first coating comprises at least one polyurethane.